

Ingredient	Quantity, mg/ml oral solution
F2: oral solution (pH = 4 ± 1)	
risperidone	0.5
tartaric acid	7.5
benzoic acid	2
Cherry flavour 1	0.25
Cherry flavour 2	0.5
sodium saccharin	1
sodium hydroxide	q.s. ad pH = 4 ± 1
purified water	q.s. ad 1 ml
F3: oral solution (pH = 3)	
risperidone	0.5
tartaric acid	7.5
sodium chloride	5
sodium saccharin	1
sodium hydroxide	q.s. ad pH = 3
purified water	q.s. ad 1 ml
F4: oral solution (pH = 5)	
risperidone	0.5
tartaric acid	7.5
sodium chloride	5
sodium saccharin	1
sodium hydroxide	q.s. ad pH = 5
purified water	q.s. ad 1 ml
F5: oral solution (pH = 3)	
risperidone	1
tartaric acid	7.5
benzoic acid	2
sodium hydroxide	ca. 1 (q.s. ad pH = 3)
purified water	q.s. ad 1 ml
F6 parenteral solution (pH = 5)	
risperidone	2
tartaric acid	7.5
sodium chloride	5
sodium hydroxide	ca. 3.75 (q.s. ad pH = 5)
water for injection	q.s. ad 1 ml

EXAMPLE 2

The tables hereinbelow summarize the risperidone concentrations measured after a particular storage time of the composition at a particular temperature, expressed as the percentage of the initial risperidone concentration.

		F1	F2
4° C.	12 months	98.2	
	1 month	100.4	101.1
	3 months	102.1	99.1
	6 months	100.9	
	9 months	99.5	
30° C.	12 months	98.7	
	3 months	102.1	98.8
	6 months	100.3	
	12 months	98.9	
40° C.	1 month	102.1	101.1
	3 months	100.9	99.4
	6 months	100.5	
	12 months	98.3	
60° C.	1 month	100.1	100.3

TABLE 2

		F3	F4
80° C.	5 days	97.9	99.0
	17 days	96.7	96.6
	4 weeks	86.2	87.6

The data in the tables indicate that compositions F1-F4 satisfy the criteria as set forth hereinbefore to qualify as a "physicochemically stable" composition.

We claim:

1. An aqueous solution suitable for oral and parenteral administration comprising water, risperidone or a pharmaceutically acceptable acid addition salt thereof, characterized in that said solution comprises a buffer to maintain the pH in the range of 2 to 6 and is essentially free of sorbitol.
2. A solution according to claim 1 wherein said pH range is obtained with a tartaric acid /sodium hydroxide buffer.
3. A solution according to claim 1 wherein the amount of risperidone ranges from 0.01% to 1% by weight based on the total volume of the solution.
4. A solution according to claim 1 having a pH ranging from 3 to 4 which is suitable for oral administration.
5. A solution according to claim 4 further comprising benzoic acid as a preservative.
6. A solution according to claim 5 containing
 - (a) 1 mg/ml risperidone;
 - (b) 2 mg/ml benzoic acid;
 - (c) 7.5 mg/ml tartaric acid and sufficient sodium hydroxide to adjust the pH in the range from 3 to 4; and
 - (d) water q.s. ad 1 ml.
7. A solution according to claim 6 further comprising one or more members selected from the group consisting of sweetening agents and flavouring substances.
8. A solution according to claim 1 having a pH ranging from 5 to 6 which is suitable for parenteral administration.
9. A solution according to claim 4 further comprising sodium chloride as an isotonicizing agent.
10. A solution according to claim 9 containing
 - (a) 1 mg/ml risperidone;
 - (b) 5 mg/ml sodium chloride;
 - (c) 7.5 mg/ml tartaric acid and sufficient sodium hydroxide to adjust the pH in the range from 5 to 6; and
 - (d) water q.s. ad 1 ml.
11. A process of preparing a solution according to claim 1 comprising the steps of
 - (a) adding the acid component of the buffer and the active ingredient risperidone to an amount of water,
 - (b) stirring the mixture until complete dissolution and cooling the solution to room temperature,
 - (c) adjusting the pH with the base component of the buffer, and
 - (d) further diluting the solution with water to the required end-volume.
12. A process according to claim 11 for preparing an oral solution as defined in claim 5 wherein step (a) is preceded by the steps of:
 - (a) dissolving the preservative in an amount of heated water, and
 - (b) diluting the solution with about an equal amount of water.
13. A process according to claim 11 for preparing an parenteral solution as defined in claim 9 wherein step (d) is preceded immediately by the step of rendering the solution about isotonic by the addition of an appropriate amount of isotonicizing agent, and is followed by autoclaving.

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